

REMARKS

After entry of this amendment, claims 1-9 and 11-13, 15-25, and 27-29 are pending. Claims 14 and 26 are canceled. Claims 1, 11, 15-17, 19, 22, 24, and 25 are amended.

I. 35 U.S.C. § 112 Rejections

Reconsideration is respectfully requested of the rejection of claims 1-9, 11, and 14-21 under 35 U.S.C. § 112, first paragraph as failing to comply with the enablement requirement. To expedite prosecution, claim 1 has been amended to recite a method of treatment of alopecia using methionine as the protective agent. Thus, because the Office recognized that claims "directed to the 'treatment' of alopecia using methionine *per se* (i.e., D-, L-, or DL-)" were "enabled by the disclosure..."¹, the amendment to claim 1 obviates the current rejection, and claim 1 and the claims that depend therefrom satisfy the requirements of 35 U.S.C. § 112.

Further, reconsideration is respectfully requested of the rejection of claims 24 and 25 as failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 24 and 25 have been amended to correct a typographical error, and thus, this rejection is moot.

II. 35 U.S.C. § 103 Rejection

Reconsideration is respectfully requested of the rejection of claims 1-9 and 11-29 under 35 U.S.C. § 103 as being unpatentable over Mathur et al. (EP 0008171) in view of Stedman's Medical Dictionary. The Office asserts that the difference between the present claims and the Mathur reference is that Mathur fails to teach the presently claimed schedule of administration.² Also, the Office asserts that finding an optimum or workable range is not inventive and would have been arrived at by routine experimentation.³

¹ Page 3 of the Office action dated September 22, 2006.

² Page 10 of the Office action dated September 22, 2006.

³ Page 12 of the Office action dated September 22, 2006.

The Marthur reference generally discloses various compositions comprising a diazole such as imidazole and histidine or histidine derivatives, and a mono basic acid such as methionine or p-amino benzoic acid, together with a physiologically acceptable carrier. These compositions are used for stimulating hair growth and/or reducing falling hair. The reference also describes various causes of chronic hair losses including X-ray treatment. The Marthur reference further describes the physical forms of their compositions as those suitable for cosmetic (i.e., topical) application to the scalp, for example, hair creams, pourable emulsion hair dressings, and alcoholic hair lotions.

However, the instant claims are directed to methods for treating alopecia using methionine compositions administered orally or parenterally and a skilled person would not have been led by the Marthur reference in combination with any other reference to arrive at the claimed methods using a methionine composition effective for treating alopecia by administration of methionine either orally or by injection.

The Stedman's Medical Dictionary passage cited by the Office is the definition of radiation of "sending forth of light, short radio waves, ultraviolet or x-rays, or any other rays for treatment or diagnosis or for other purpose; irradiation."⁴ Thus, even if a skilled person would have considered combining the teachings of Marthur and Stedman's Medical dictionary, the skilled person knowing the different mechanisms of topical delivery, oral delivery, and parenteral delivery would not have had a reasonable expectation that the claimed methods using methionine would be successful for administration orally or parenterally.

Further, the Marthur disclosure fails to provide a person of ordinary skill enough information to convert the formulation for the cosmetic application to the scalp to a formulation appropriate for use in a method of treatment for oral or parenteral administration of the methionine protectant contemplated by the pending claims. A person of ordinary skill understanding the differing mechanisms for oral and parenteral administration as compared

⁴ Stedman's Medical Dictionary, 22nd Ed., 1972.

to topical administration, would have known that the difference in absorption rates, transport, and metabolism of biologically active compounds for each method of administration would not have allowed a skilled person to arrive at the claimed methods from the combined teachings of Marthur and Stedman's Medical Dictionary. Thus, there would not have been a reasonable expectation that such a formulation would be effective as a protectant for alopecia arising from radiation exposure as required by claims 1 and 22. In sum, claims 1 and 22, and the claims that depend therefrom are patentable over Marthur in view of Stedman's Medical Dictionary under 35 U.S.C. § 103(a).

III. The Claimed Methods are Not *prima facie* Obvious in View of the Claims of the Cited Patents.

Reconsideration is requested of the rejection of claims 1-9 and 11-29 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 35 and 36 of U.S. Patent No. 6,187,817.

The analysis employed in an obvious-type double patenting rejection parallels the guidelines of a 35 U.S.C. § 103 obviousness determination.⁵ However, an important distinction exists. A rejection for obviousness must be based on a comparison of the claimed invention to the entirety of the disclosure in the prior art reference, whereas an obviousness-type double patenting rejection must be grounded on a comparison of the claimed invention to the claims, **and only the claims**, of the reference.⁶

It is respectfully submitted that the subject matter of the claims of the present application would not have been obvious in view of claims 35 and 36 of U.S. Patent Nos. 6,187,817. When evaluating the scope of a claim, every element of the claim must be considered.⁷ To support an obviousness-type double patenting rejection, the claims must have been obvious at the time of filing and not merely obvious upon hindsight reconstruction using applicant's disclosure as a template to arrive at the features of the instantly claimed

⁵ *In re Braat*, 937 F.2d 589 (Fed. Cir. 1991).

⁶ *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 98 F.Supp.2d 362, 392, 55 USPQ2d 1168, 1190 (S.D.N.Y. 2000), *aff'd*, 237 F.3d 1359, 57 USPQ2d 1647 (Fed. Cir. 2001).

⁷ See, e.g., *In re Ochiai*, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995).

methods from the claims of the '817 patent. It is respectfully submitted that the Office has failed to establish obviousness based on this reference, or by evidence of the level of skill in the art or the nature of the problem, that is not based upon impermissible hindsight reconstruction.

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Claims 1-9 and 11-29 of the instant application are directed to methods for treating alopecia in a patient exposed to radiation, the method comprising administering to said patient an effective amount of a protective agent. In contrast, claims 35-36 of the '817 patent are directed to methods of preventing or reducing alopecia arising from treatment with a chemotherapeutic effective amount of an anti-tumor platinum-coordination compound. Accordingly, because claims 35 and 36 of the '817 patent are not directed to protection of toxicities arising from radiation exposure, the claims do not include all the elements of the subject claims.

The Office asserts that the cause of the alopecia (e.g., arising from administration of an anti-tumor platinum-coordination compound or arising from radiation exposure) "fails to impart patentable distinction to the present claims over the patented claims because both the present claims and the patented claims are primarily directed to the treatment of alopecia."⁸ However, a person of skill in the art would have known that the mechanisms of cell damage are different for different insults (e.g., platinum-coordination compounds versus radiation) and would not have known that a protective agent for toxicities arising from platinum-coordination compounds would necessarily be effective as a protective agent against toxicities arising from radiation. Certainly nothing in the '817 claims suggests treating radiation-induced alopecia with a methionine compound. Moreover, without applicant's own disclosure regarding the protection against alopecia arising from radiation, a person of ordinary skill would not have found the instant claims obvious from any combination of the '817 claims and the cited art. Thus, the subject claims would not have been obvious from the claims of the '817 patent.

⁸ See Office action dated September 22, 2006 at page 14.

In summary, a person of ordinary skill would not have found the instant methods for the treatment of alopecia arising from exposure to radiation obvious upon consideration of claims 35 and 36 of the '817 patent. It is, therefore, respectfully requested that the double patenting rejection over claims 35 and 36 of the '817 patent be withdrawn.

Moreover, without conceding the propriety of the rejection, it is noted that the present application claims priority as a continuation of various applications which matured into the '817 patent. A terminal disclaimer, therefore, would not further limit the term of any patent maturing from this application; if it would advance prosecution, therefore, applicant would consider filing a terminal disclaimer with respect to the '817 patent.

CONCLUSION

Applicant submits that the present application is now in a condition for allowance and requests early allowance of the pending claims.

The Commissioner is hereby authorized to charge any underpayment and credit any overpayment of government fees to Deposit Account No. 19-1345.

Respectfully submitted,

A handwritten signature in black ink, reading "Janet S. Hendrickson". The signature is fluid and cursive, with a long, sweeping underline that extends to the right.

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